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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/805,337	03/13/2001	Brendan F. Murphy	DI-5585L (BXTD 9000.1)	1925

7590 04/28/2003

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EXAMINER	
CHISM, BILLY D	
ART UNIT	**PAPER NUMBER**
1654	12

DATE MAILED: 04/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/805,337	MURPHY, BRENDAN F.	
	Examiner	Art Unit	
	B. Dell Chism	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-30* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-2, drawn to a factor H-related protein 5 or a fragment thereof, classified in class 514, subclass 8.

II. Claims 3-11, drawn to a polynucleotide encoding a factor H-related protein 5 or a fragment thereof, classified in class 536, subclass 23.4.

III. Claims 12-13, 15-21 and 23-28, drawn to a polyclonal antibody to a factor H-related protein 5 or a fragment thereof, classified in class 530, subclass 389.1.

IV. Claims 12, 14-20, 22-28, drawn to a monoclonal antibody to a factor H-related protein 5 or fragment thereof, classified in class 530, subclass 388.1.

V. Claims 29-30, drawn to a method for detection of C5b-9complement complexes comprising binding polyclonal antibodies to the target compound, classified in class 435, subclass 7.1.

VI. Claims 29-30, drawn to a method for detection of C5b-9complement complexes comprising binding monoclonal antibodies to the target compound, classified in class 435, subclass 7.1.

2. The inventions are distinct, each from the other because:

Groups I and II are distinct wherein the Group II polynucleotide and the Group I protein are related since the DNA encodes the claimed protein. They are distinct inventions because they are physically and functionally distinct entities, and the protein product can be made by another

and materially different process, such as by synthetic peptide synthesis. Further, the DNA may be used for processes other than the production of the protein, such as in a hybridization assay.

The proteins of Group I are related to the antibodies of Groups III-IV and related to the methods of using the antibodies of Groups V-VI by virtue of being the cognate antigen, necessary for the production of antibodies. Although the proteins and antibodies are related due to the necessary stearic complementarities, they are distinct inventions because the protein can be used in another and materially different process from the use for the production of the antibody or in the detection assays using the antibodies, such as in a pharmaceutical composition in its own right, or to assay or purify the natural ligand of the protein (if the protein is itself a receptor), or in assays for the identification of agonists or antagonists of the receptor protein.

Groups II and III-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polynucleotides of Group II are for the production of the proteins of Group I, and the antibodies and methods of using the antibodies are for detection of proteins not requiring the polynucleotide of Group II.

Groups III and Group IV are different and distinct wherein the two products are different in structure and function and have differing effects.

Groups III and V are distinct inventions as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be use in a materially different process of using that product (MPEP §

806.05(h)). In the instant case the antibodies of Group III can be used for purification assays, therapeutics or diagnostic assays.

Groups III and VI are distinct inventions wherein the product of group III is neither made by the methods of group VI nor is the product of group III used in the methods of group VI.

Groups IV and V are distinct inventions wherein the product of group IV is neither made by the methods of group V nor is the product of group IV used in the methods of group V.

Groups IV and VI are distinct inventions as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be use in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies of Group IV can be used for purification assays, therapeutics or diagnostic assays.

Groups V and VI are distinct inventions wherein the two groups of methods are independent, using separate method steps, active agents, and having different effects.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and the search required for one group is not required for another group, restriction for examination purposes as indicated is proper.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism whose telephone number is 703-306-5815. The examiner can normally be reached on 7:30 AM - 4:30 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 703-306-3220. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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B. Dell Chism
22 April 2003

Brenda Brumback
BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600